

REMARKS

By the foregoing amendments, claims 13 and 14 have been amended. Support for the amendment to claim 13 can be found in original claim 14. Claims 1-12 have been withdrawn from consideration. Claims 13-17 are under examination.

Applicants request an Examiner-initialed copy of the PTO-1449 form submitted with the Information Disclosure Statement submitted on September 3, 2008. A copy of the Information Disclosure Statement (without the references) is attached for the Examiner's convenience.

The Rejection under 35 USC § 112, Second Paragraph

Claim 14 is rejected under Section 112, second paragraph, as indefinite for recitation of "preferably." By the foregoing amendment, this term has been deleted from the claim and withdrawal of the rejection is respectfully requested.

The Rejection under 35 USC § 102(b)

Claim 13 is rejected under Section 102(b) over Guez et al., WO 99/25374, having the English equivalent of US 6,653,336. The '336 patent teaches compositions comprising perindopril, indapamide, lactose and microcrystalline cellulose. Product sheets from the internet relating to microcrystalline cellulose are relied upon to demonstrate the availability of low moisture cellulose.

In the interest of expediting prosecution, Applicants have amended claim 13 to indicate that the inorganic carbonate is not optional, and that the molar ratio of perindopril to inorganic carbonate is 1 to 0.1-0.9.

Anticipation requires that a single reference teach each and every element set forth in the claim (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir 1987)). Guez et al. do not teach or suggest the presence of carbonate in its compositions. It is respectfully requested that the rejection of claim 13 under Section 102(b) be withdrawn.

The Rejection under 35 USC § 103(a)

Claim 14 is rejected under Section 103(a) over Guez et al. in view of Eyjolfsson, WO 99/25374. Eyjolfsson is relied upon for its teaching of a wide concentration range (i.e., 5-90 wt%) of carbonates as stabilizers for ACE compounds (page 3, line 8). However, Eyjolfsson states that in preferred embodiments, “the amount of the alkaline earth metal carbonate is at least the equivalent of the amount of the active compound,” specifically at least twice or three times the equivalent (page 3, lines 27-30). The Examiner argues that it would be routine optimization to identify the lower range, i.e., less than 1:1 molar equivalent.

Applicants respectfully submit that claim 14 is not obvious by virtue of its dependency on claim 13, which recites that the molar ratio of perindopril to inorganic carbonate is 1 to 0.1-0.9.

A *prima facie* case of obviousness based on overlapping ranges with the prior art can be rebutted by showing the criticality of the claimed range. The applicant must show that the claimed range achieves an unexpected result relative to the prior art range. MPEP § 2144.05 (III) citing *In re Woodruff*, 16 USPQ2d 1934 (Fed. Cir. 1990). MPEP § 2144.05 (III) also cites *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 73 USPQ2d 1225 (Fed. Cir. 2004) for the rule that Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing “(1) [t]hat the prior art taught away from the claimed invention . . . or (2) that there are new and unexpected results relative to the prior art.”

Applicants refer to page 6, lines 1-5, of the subject specification, wherein it is stated that it was “surprising that the use of small amounts of inorganic carbonate, i.e., below the stoichiometric amount, provide an additional stabilizing effect even though according to the prior art at least stoichiometric amounts need to be used.” There is nothing in Eyjolfsson that specifically directs the skilled artisan to the use of less than a stoichiometric amount and to the recited molar ratio of 1 to 0.1 to 0.9. In fact, and as acknowledged by the Examiner, Eyjolfsson emphasized that at least a 1:1 molar ratio or stoichiometric amount of carbonate should be used to obtain preferable results. This constitutes a teaching away from using amounts of carbonate less than a 1:1 molar ratio or a stoichiometric amount.

Further, according to the subject specification, the recited molar range of 1 to 0.1 to 0.9 unexpectedly reduces the production of diketopiperazine (DKP), an intramolecular cyclization product (page 1, lines 16-18; page 6, lines 1-5; and page 9, Example 3). The unexpected improvement associated with this range establishes the non-obviousness of claim 13 and withdrawal of the Section 103 rejection of claim 14 is therefore respectfully requested.

Claims 15-17 are rejected under Section 103(a) over Guez et al. in view of www.signetchem.com, and further in view of Cooper et al., U.S. Publication 2003/0232796. Applicants respectfully traverse the rejection.

As is discussed above, claim 13, from which claims 15-17 depend, has been amended to recite that carbonate is present in an amount wherein the molar ratio of perindopril to carbonate is 1 to 0.1-0.9. Nothing in www.signetchem.com or Cooper et al. teach or suggest this molar ratio range for perindopril to carbonate. It is therefore submitted that claim 13 and dependent claims 15-17 are non-obvious over the combination of Guez et al., www.signetchem.com and Cooper et al. Withdrawal of the subject rejection is respectfully requested.

Closing Remarks

It is believed that the foregoing amendments and remarks bring the subject case into condition for allowance and notification of same is respectfully requested. If it is believed that a phone conference would expedite prosecution, the Examiner is invited to phone the undersigned at 303-268-0066.

Submitted herewith is a Petition for Extension of Time for one month with an authorization to charge the extension fee to Deposit Account No. 19-5117. It is believed that no other fees are due with this submission. If this is in error, please charge any necessary fees to Deposit Account No. 19-5117.

Respectfully submitted,

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Date

/Margaret M. Wall/

Margaret M. Wall, #33,462
Swanson & Bratschun, LLC
8210 Southpark Terrace
Littleton, CO 80120
303-268-0066

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